

Confidentiality Note:

The information contained in this facsimile message is confidential and its contents are intended to be legally privileged information solely for the use of the addressee. If the reader of this message is not the intended recipient, you are hereby notified that any dissemination, distribution, copying or other use of this message and its contents is strictly prohibited. If you have received this facsimile in error, please notify us immediately by telephone and return the original message to us at the address shown below via air courier service, the United States Postal Service or your national postal service (air mail). Thank You.

ALSTON & BIRD LLP

3201 Beechleaf Court, Suite 600
Raleigh, NC 27604-1062

919-862-2200
Fax: 919-862-2260

**RECEIVED
CENTRAL FAX CENTER**

FEB 18 2005

TELECOPY

PLEASE DELIVER AS SOON AS POSSIBLE

DATE: February 18, 2005

TO: Commissioner for Patents

FROM: Kelly J. Williamson
Patent Agent

In re: Stein *et al.*
Appl. No.: 09/973,375
Filed: October 9, 2001
For: METHODS FOR THE TREATMENT OF A TRAUMATIC CENTRAL
NERVOUS SYSTEM INJURY

Confirmation No.: 5877
Group Art Unit: 1617
Examiner: S. Jiang

Attachments:
Supplemental Amendment (10 pages)
Interview Summary (3 pages)

NO. OF PAGES: 14
(Including cover page)

OPERATOR:

IF NOT RECEIVED PROPERLY, PLEASE NOTIFY ME IMMEDIATELY AT (919) 862-2200

USER CODE: LAKE

FAX NUMBER: (703) 872-9306

CLIENT/MATTER: 007157/239838

REQUESTED BY: Pam Lockley

VOICE NUMBER:

Attorney's Docket No. 007157/239838 (5543-17)PATENT**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re:	Stein <i>et al.</i>	Confirmation No.: 5877
Appl. No.:	09/973,375	Group Art Unit: 1617
Filed:	October 9, 2001	Examiner: S. Jiang
For:	METHODS FOR THE TREATMENT OF A TRAUMATIC CENTRAL NERVOUS SYSTEM INJURY	

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INTERVIEW SUMMARY

Sir:

An interview in the above-referenced matter occurred on February 8, 2005 between Examiner Jiang and Applicants representatives Murray Spruill and Kelly Williamson. Applicants provide below a summary of the interview.

The Amendment and Response filed on February 1, 2005 was discussed. Specifically, claims 1-13 and 15-20 were discussed in view of the inherency rejections under 35 U.S.C. §102.

1. Applicants emphasized that Roof *et al.* (1997) and Roof *et al.* (1992) do not anticipate claims 1-13 and 15-20. Both Roof *et al.* references disclose the administration of progesterone to a subject. In contrast, the claims of the instant invention recite the administration of a pharmaceutical composition comprising allopregnanolone. As neither of the Roof *et al.* references administers this pharmaceutical composition, claims 1-13 and 15-20 are novel.

To expedite prosecution, the Examiner proposed amending claim 1 to more clearly recite that the pharmaceutical composition being administered comprised an effective amount of allopregnanolone.

RTA01/2175194v1

Appl. No.: 09/973,375

Amdt. dated 02/18/2005

Reply to Office action of November 4, 2004

2. Applicants emphasized that *Gee et al.* (RE 35,517) does not teach the administration of allopregnanolone to the same patient population as set forth in claims 1-7, 13 and 16-17 and does not anticipate the claims.

Gee et al. suggests methods of modulating brain excitability to alleviate stress, anxiety, and seizure activity. However, the claims of the instant invention are drawn to "a method of treating a traumatic central nervous system injury" (claims 1-15), and "a method of decreasing neurodegeneration on a population of cells in a subject following a traumatic injury to the central nervous system" (claims 16-20). It was discussed that page 6, lines 17-23 of the specification recites, "[a] traumatic injury to the CNS is characterized by a physical impact to the central nervous system." *Gee et al.* does not teach or suggest administering any progesterone metabolite to a subject following a traumatic injury (i.e., physical impact) to the CNS. The claims of the instant invention are not inherently taught by *Gee et al.*

To expedite prosecution, the Examiner proposed amending claim 1 to more clearly recite the patient population being treated.

3. Applicants emphasized that *Tauboll et al.* (1993) does not teach the administration of allopregnanolone to the same patient population as set forth in claims 1-7 and 12-13 and does not anticipate the claims.

Tauboll et al. teach that administration of allopregnanolone increases the seizure threshold in a dose dependant manner when seizures were produced via an electrical stimulation in the primary visual cortex of a cat. The cats employed by *Tauboll et al.* did not suffer a "physical impact" and accordingly, the reference does not teach the administration of allopregnanolone following a traumatic injury as recited in claims 1-7 and 12-13. Once again, the patient population being treated by *Tauboll et al.* is not the same as the patient population recited in the instant claims.

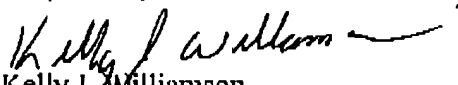
To expedite prosecution, the Examiner proposed amending claim 1 to more clearly recite the patient population being treated.

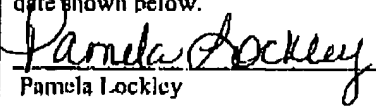
Appl. No.: 09/973,375
Amdt. dated 02/18/2005
Reply to Office action of November 4, 2004

In view of the Examiner's suggestions, it was agreed a supplemental amendment would be filed in Response to the Office Action of November 4, 2005.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those, which may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,


Kelly J. Williamson
Patent Agent
Registration No. 47,179

<p>Customer No. 00826 ALSTON & BIRD LLP Bank of America Plaza 101 South Tryon Street, Suite 4000 Charlotte, NC 28280-4000 Tel Raleigh Office (919) 862-2200 Fax Raleigh Office (919) 862-2260</p>	<p>CERTIFICATION OF FACSIMILE TRANSMISSION I hereby certify that this paper is being facsimile transmitted to the U.S. Patent and Trademark Office Fax No. (703) 872- 9306 on the date shown below.  Pamela Lockley Date 2/18/05</p>
--	---